SENSOR DISPENSING DEVICE

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This application claims priority to co-pending United States provisional application serial number 60/441,503 filed on January 21 2003, which is entitled "SENSOR DISPENSING DEVICE" the disclosure of which is incorporated herein by reference. This application also claims priority to United Kingdom patent application serial number 0300765.5 filed JANUARY 14 2003, which is entitled "SENSOR DISPENSING DEVICE" the disclosure of which is also incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a device for dispensing sensors for measuring the concentration of an analyte in a fluid sample (notably glucose in whole blood), and to a cartridge containing sensors for use in the device. The invention also provides a meter incorporating the dispensing device.

2. Description of the Prior Art

Diabetics regularly need to test samples of their blood to determine the levels of blood glucose. In one known type of test system, disposable sensors are used to test the

blood. The sensors typically take the form of test strips which are provided with a reagent material that will react with blood glucose to produce an electrical signal. Conductive tracks on the test strip relay the electrical signal to a meter which displays the result. After a sample of blood has been applied to the test strip and the measurement has been taken, the test strip is disposed of. Examples of test devices with test strip dispensers are described in US Patent No. 5,660,791, and European Patent Application Numbers 0 732 590, 0 738 666, and 0 811 843.

A problem with test strips is that they have only a limited shelf life, and exposure of test strips to the atmosphere further reduces the shelf life.

In DE 196 39 226 A1 it is proposed to provide a test device with a cartridge that may have a plurality of chambers containing test strips, each of which chambers may be individually sealed to preserve the shelf life of the strips therein. A user removes the seal for each chamber when required, and a timing circuit may be activated either by the user or when the cartridge is pushed into the device. After a set time period has elapsed, an alarm or other indication reminds the user that the time period for using the strips has elapsed. WO 02/08753 describes a blood glucose meter which has test strips arranged in a plurality of stacks in a magazine. Each stack is individually sealed, and the stack's seal is broken automatically when the magazine moves to a location where a test member can be dispensed by means of a suitable pusher.

It has been proposed in WO 94/10558 to provide a stack of disposable sensors in a cylindrical housing, the stack being urged towards a test station to form a liquid-proof seal. In WO 02/18940 there is disclosed a blood glucose test meter in which a stack of test strips in a replaceable cartridge are sealed against a rotatable transport member which is adapted to receive a single test strip and rotatably transport the test strip while maintaining a seal around the cartridge.

A problem with such systems is that the sealing means may wear with repeated use and the quality of the seal may consequently be reduced.

US 5,759,010 discloses a cartridge for dispensing slide test elements of the kind which have an opening for liquid access. The cartridge is provided with an internal cover plate which is biased to make a sealing contact with the opening so as to protect the inside of the opening from atmospheric moisture before the slide is dispensed. Such an arrangement is less desirable for test members in which the reagents are not located in an opening of a moisture-impermeable slide member because it is difficult to make a reliable seal around the reagents. Friction between the reagent layer and the plate may also tend to abrade the reagent layer.

It is an object of the present invention to provide an improved test device. It is a further object of the invention to provide an improved dispenser for sensors for

use in measuring analyte concentration in an applied fluid.

SUMMARY OF THE INVENTION

According to an aspect of the present invention there is provided a sensor dispensing device for dispensing sensors for testing of analyte concentration in a fluid to be applied thereto, the device comprising:

a cartridge having an outer casing and a plurality of sensors arranged one upon another in a stack therein;

the cartridge having a first dispensing end and a second opposing end spaced a fixed distance apart, and the cartridge including a first aperture for the ejection of a sensor closest to the first end and a second aperture opposed to the first aperture, for access by a pushing member;

wherein the first aperture and the second aperture are each provided with compliant sealing means which are carried by the cartridge and which are at least partly disposed outside the outer casing, the sealing means having first and second sealing surfaces which are capable of co-operating to releasably form a substantially moisture-tight seal when acted upon by suitable clamping forces;

the device further comprising:

a housing for receiving the cartridge;

for each of the said compliant sealing means, a pair of clamping members for releasably clamping the sealing means to form a substantially moisture-tight seal; and

a pushing member for reversible insertion through the

second aperture when the sealing means are not clamped, for pushing the sensor closest to the first end through the first aperture to a dispensed position.

By providing the sealing means on the cartridge, problems of wear are reduced because the seals are replenished each time the cartridge is replaced.

In a preferred embodiment each of the sealing means comprises a tube of a natural or synthetic rubber material. Suitable materials include styrene-ethylene-butylene-styrene (SEBS), for example Thermoflex™, ethylene-propylene-diene monomer (EPDM) terpolymer, optionally alloyed with other materials such as polypropylene. Preferred materials are thermoplastic elastomers, for example Santoprene™, a nitrile rubber mixed with polypropylene, or thermoplastic polyurethane elastomers, for example Pellethane™. A preferred material is a mixture of Thermoflex™ 45A with Nourymix™ SP E60 antistatic/slip agent (from Akzo Nobel Chemicals). Nourymix™ SP E60 comprises 80% of a rapeseed oil-based erucamide (13-docosenamide) on a polypropylene carrier. The additive helps to prevent sticking of the tubular elastomer after being clamped for a length of time. The concentration of Nourymix™ is preferably in the range 0.2 to 5%, notably about 3%. Each tube may be disposed through its associated aperture and be a close fit for this aperture. Thus, when the tubes are suitably clamped or nipped the inside of the cartridge is sealed from moisture.

The compliant sealing means may alternatively comprise a pair of opposed sealing surfaces of rubber or other elastomeric material which do not form part of a tube. The pushing member passes between two sealing surfaces on the cartridge when it enters the second aperture, and a sensor passes between two sealing surfaces on the cartridge when it is dispensed from the cartridge. For convenience the invention will be described with reference to the use of a tubular rubber sealing member, but it will be understood that the invention is not limited to this embodiment.

A separate pair of clamping members may be provided for each sealing member. However, in a preferred embodiment a single pair of clamping members may serve to clamp both sealing members. For simplicity it is preferred that one clamping member is fixed while the other is movable, although both clamping members could of course be movable if desired. It is preferred that both clamping members of the pair are provided in or on the housing; however, it would be possible to provide one clamping member (notably, a fixed clamping member) on the cartridge.

The pusher is preferably flexible so that it can be coiled on a drum or other suitable support so that the device may be made compact. A running guide may be incorporated into the cartridge mouldings so that the pusher will be supported throughout its travel through the cartridge to facilitate reliable dispensing of a thin test strip. Provision of a guiding slot creates the potential for the pusher to be moulded as a single component, for example of

acetal.

The sensor in the dispensed position may be taken by the user and used in a conventional test meter. In a preferred embodiment, however, the device further comprises signal-reading means for determining the concentration of an analyte in an applied sample according to a signal generated by the sensor in the dispensed position. The signal-reading means may comprise electronic circuitry for measuring an electric signal generated by the sensor in response to analyte concentration in an applied sample. With the sensor in the dispensed position its electrodes engage with contacts connected to the circuitry, in known manner. Alternatively, the signal-reading means may measure an optical change in the sensor, for example a colour change. Many suitable signal-reading means are known to those skilled in the art. With the inclusion of signal-reading means the device is a meter for measuring analyte concentration in a fluid. For convenience hereinafter the invention will be described with reference to its embodiment in a blood glucose meter, but it will be understood that the invention is not limited to this application.

The cartridge may be sold as a separate item for refilling the sensor dispensing device or meter. Accordingly, another aspect of the invention provides a cartridge comprising:

an outer casing and a plurality of sensors arranged one upon another in a stack therein, each sensor being for testing of analyte concentration in a fluid to be applied

thereto;

the cartridge having a first dispensing end and a second opposing end spaced a fixed distance apart, and the cartridge including a first aperture for the ejection of a sensor closest to the first end and a second aperture opposed to the first aperture, for access by a pushing member;

wherein the first aperture and the second aperture are each provided with compliant sealing means which are at least partly disposed outside the outer casing, the sealing means having first and second sealing surfaces which are capable of co-operating to releasably form a substantially moisture-tight seal when acted upon by suitable clamping forces.

The housing may contain a desiccant to absorb moisture. In a preferred embodiment, the cartridge inner assembly or a component thereof, for example a sprung follower, may be formed from a desiccant plastics material. Suitable desiccant plastics materials are known in the art and may be obtained from CSP Technologies, Bourne End, Bucks, UK.

It is preferred that spring means are provided in the cartridge for urging the stack of sensors towards the dispensing end. Any suitable spring means may be used and are well known to those skilled in the art. Examples are coil or compression springs, elastic members, or pneumatic or motorised pushing members. It is preferred that the spring means are constant tension springs to provide controlled movement of the stack within the housing.

The cartridge may optionally contain a calibration strip which will be the first strip to be dispensed, to enable calibration of the meter for the batch of strips therein.

Other aspects and benefits of the invention will appear in the following specification, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be further described, by way of example only, with reference to the following drawings in which:

Figure 1 is a sectional view from underneath a blood glucose meter according to a first embodiment of the invention;

Figure 2 is a simplified cutaway view from the right side of the meter of Figure 1;

Figure 3 is a top view of the blood glucose meter of Figures 1 and 2;

Figure 4 is an end elevation view of a cartridge for the meter of Figures 1 to 3 in accordance with an embodiment of a further aspect of the invention;

Figure 5 is sectional view along the lines I-I of Figure 4;

Figures 6-8 are part-sectional views through the meter of Figure 3 from above the meter, from the handle end of the meter, and from below the meter respectively;

Figure 9 is a perspective view of an embodiment of a rubber sealing member for use in the invention;

Figures 10 to 14 are simplified perspective views of parts of a blood glucose meter in accordance with another embodiment of the invention;

Figures 15 and 16 are perspective views showing details of the latch spring mechanism of an embodiment of the invention;

Figures 17 and 18 illustrate alternative drive mechanisms in accordance with still further embodiments of the invention;

Figure 19 is an exploded view of one embodiment of a cartridge inner assembly for the cartridge of Figure 5; and

Figures 20 and 21 illustrate stages in the assembly of an alternative embodiment of a cartridge inner assembly for the cartridge of Figure 5.

DETAILED DESCRIPTION

In the embodiments illustrated in the drawings, parts which perform the same function will be denoted by the same numbers.

The blood glucose meter 1 shown in Figures 1 to 3 comprises an outer casing 3 which houses a cartridge 2 and a delivery mechanism 5 for dispensing test strips 6 from the cartridge 2. The casing 3 also houses a moveable clamp 4 for sealing the inside of the cartridge 2 from

atmospheric moisture, as will be described in more detail below. The external features of the meter 1 comprise control buttons 50 for controlling the operation of the meter, an LCD 8 for displaying user instructions, results and other data, and an external handle 9 for actuating the delivery mechanism. A control PCB 7 is operably connected to the LCD 8 and buttons 50. The meter 1 of Figures 1-3 is shown with a test strip 6 in a dispensed position ready to receive a drop of blood.

Referring now to Figures 4 and 5, the cartridge 2 has an inner assembly 12 and an outer casing 11, in this example formed from polypropylene, sealingly covered by a cap 10. The cartridge has a first, dispensing, end 13 and an opposing end 14 which in this embodiment includes the cap 10. The cap 10 may be welded to the remainder of the outer casing, for example by ultrasonic welding, to form a fluid-tight bond. Instead of a cap, the outer casing may be closed by foil, for example of aluminium, or other suitable sealing member.

A stack of test strips 6 is housed in the cartridge inner assembly 12, and the strips 6 are urged towards the dispensing end by a constant tension spring 19 which acts on a follower 18. At the dispensing end 13 there are opposed first 15 and second 16 apertures, each of which is provided in this embodiment with a co-moulded tubular rubber sealing member 17, as best shown in Figure 9. The sealing members 17 comprise a first sealing lip 17a and a second sealing lip 17b, each sealing lip providing a sealing surface. In this embodiment, the sealing surfaces

are provided as part of a single tubular member 17, but they could alternatively be separately provided. When the sealing members 17 are open they permit a pusher to be inserted through one aperture to push a test strip 6 through the other aperture. When the sealing members 17 are clamped shut, the inside of the outer casing 11 is substantially sealed off from atmospheric moisture. The cartridge 2 will be kept in a moisture-tight container (not shown) until immediately prior to its insertion into the meter 1.

One way of manufacturing the cartridge inner assembly 12 is illustrated in the exploded diagram shown in Figure 19. The walls of the cartridge inner assembly 12 are formed from a base member 50 and a closure member 51. Two opposed upstanding walls of the base member 50 are provided with a series of ridges 52 in which fit arms 53 of the follower 18. The ridges 52 and arms 53 are profiled to permit movement of the follower 18 in one direction only, towards the stack of test strips 6. During assembly, the follower 18 is located near to the spring 19 to permit the stack of strips 6 to fit in the base member 50. The closure member 51 is snap-fitted on the base member 50 to form the cartridge inner assembly 12. A lip 54 on the closure member 51 provides a stop member which limits outward travel of the strips 6. There is a sufficient gap between the lip 54 and the adjacent walls of the base member 50 (which define opposed openings of the housing) to permit a single strip 6 to slide out axially. An alternative design of cartridge inner assembly 12 is shown in Figures 20 and 21. Here, the stop

member 54 is provided on the base member 50.

Referring now to Figures 6-8, the working parts of the meter 1 are mounted on a chassis comprising a first chassis member 29 and a second chassis member 30. The cartridge 2 is received in a cartridge-receiving portion 34 in the meter casing 3. A lid 33, is closed over the dispensing end of the cartridge 2 and provides a shoulder on which the tubular sealing members 17 rest. The clamp 4 is urged towards the lid 33 by a clamping spring 28. The clamp 4 is operatively connected to by a clamp arm 20 to a rotatable arm lift cam 21. In the rest position shown in Figure 6, the bottom edges of the clamp 4 exert a clamping force on the tubular sealing members 17 so as to clamp the sealing members 17 between the clamp 4 and inner surfaces of the lid 33, thereby providing a substantially fluid-tight seal to protect the inside of the cartridge 2 from the external atmosphere. The delivery mechanism comprises a pusher drum 36 on which is wound an axially elongate pusher 25, and a drive drum 31 which has a drive handle 32 operatively connected to the external handle 9 of the meter. A latch spring 24 is provided on the drive drum 31 for releasably engaging the drive drum 31 with the pusher drum 36. It will be understood that the drive drum and the pusher drum need not be hollow, and could comprise solid cylinders, wheels, discs or the like. It is preferred that the drums are substantially circular in cross section, but other shapes such as an oval could also be used.

In the rest position the latch spring 24 is disengaged by

a ramp 35 which is part of the second chassis member 30, as best shown in Figure 16. As the user operates the external handle 9, the handle 32 of the drive drum turns the drive drum 31. The drive drum 31 is free to turn through a set angle with the latch spring 24 turning with it. A drive spring 22, which connects the drive drum 31 directly or indirectly to the chassis, is wound up. Nothing happens to the pusher 25 during the initial turning as it is held with a one-way ratchet feature. If the user releases the drive drum at this point the mechanism will return to the rest position without dispensing a test strip 6. At the "point of no return" the latch spring 24 drops into a slot on the pusher drum 36, effectively locking the two drums together. At this point the pusher 25 is in its rest position. When the user lets go the handle 9, the drive drum 31 and pusher drum 36 are forced to rotate by the wound-up drive spring 22. During this rotation three things happen:

the arm lifting cam 21 lifts the clamp arm 20 to open the tubular sealing members 17 (Figure 8);

the flexible pusher 25 forces a test strip 6 from the cartridge 2 to a dispensed position under meter contacts 27 within a contact block 26; and

a return spring 23, which connects the pusher drum 36 directly or indirectly to the chassis, is wound up.

At the end of the rotation of the drive drum 31, the latch spring 24 is lifted out of the slot in the pusher drum 36 by the ramp 35. The relative positions of the latch spring 24 before and after engagement with the ramp 35 are illustrated in Figures 15 and 16 respectively.

When the pusher drum 36 is released from the drive drum 31 it returns to its rest position by the action of the return spring 23. At the end of this rotation the arm lift cam 21 permits the clamp arm 20 to drop and re-establish a clamping force across the sealing members 17.

Referring now to Figure 10, a simplified view of an alternative embodiment of the invention illustrates the location of the test strip 6 prior to being dispensed. The pusher 25 is in an undeployed state. In Figure 11 the arm lift cam 21 has lifted the clamp arm 20 and the clamp 4. The pusher 25 has been deployed so as to push the test strip 6 to the dispensed position where its electrodes are in contact with meter contacts in the contact block 26. The pusher 25 is no longer fully deployed and is in the process of being retracted onto the pusher drum. Simplified figures 12-14 illustrate parts of the meter with the cartridge 2 at different stages of insertion.

The delivery system of the meter is mechanically robust and uses simple moulded components. The mechanism permits a more symmetrical product to be manufactured because the delivery mechanism 5 sits behind the cartridge 2, as best shown in Figure 12. The mechanism may be operated by either rotary or linear user activation. Alternative mechanical systems to control clamping of the sealing members and co-ordinated deployment of the pusher are described below with reference to Figures 17 and 18.

The delivery mechanism illustrated in Figure 17 comprises drive disc 37 on which is mounted a pin 38. The drive

disc 37 is connected to the arm lift cam 21 (not shown). A first transfer pinion 39 and a second transfer pinion 41 are provided with, respectively, first 40 and second 42 transfer blades. The transfer pinions 39, 41 are rotatably mounted in relation to the drive disc 37 and their teeth are interengaged. The second transfer pinion 41 is directly linked to the pusher drum 36. The mechanism works as follows.

1. With the mechanism arranged as in Figure 17a, the user winds the activating handle through 120°.
2. This action winds up the drive spring which is connected to the drive disc 37.
3. Once the user passes the "point of no return" the drive disc 37 is free to begin its 360° rotation using the energy stored in the drive spring (Figure 17b).
4. This rotation forces the pin 38 on the drive disc 37 to push on the first transfer blade 40 which pushes the first transfer pinion 39 through 180°.
5. Pushing the first transfer pinion 39 clockwise makes the second transfer pinion 41 rotate counter-clockwise as they are directly meshed together. Turning of the second transfer pinion 41 turns the pusher drum 36 and the flexible pusher 25 is deployed (Figure 17c) and forces a test strip to the deployed position.
6. After 180° of rotation the pin 38 slips off the first transfer blade 40 and begins to act on the second transfer pinion 41 *via* the second transfer blade 42. This reverses the direction of the pusher drum 36, retracting the pusher 25 (Figure 17d).
7. At the end of the 360° rotation of the drive disc 37,

the pin 38 slips off the second transfer blade 42 returning the mechanism to the rest state and completing the mechanical movement (Figure 17e).

This system can readily be driven by an electric motor because the drive disc is driven in only one direction. Alternatively, it may be actuated by either linear or rotary user activation. It uses simple moulded components, some of which are repeated. This mechanism can also be located behind the cartridge, permitting a symmetrical product design. Because the mechanism self-reverses, no opposing spring force is required.

Referring now to Figure 18, a further alternative delivery mechanism is illustrated, which uses a rack and pinion arrangement. The mechanism works as follows:

1. The user pulls back the external handle; this pulls back a slide 43 from the rest position shown in Figure 18a and winds up the return spring. The slide 43 is provided with a rack 44 for engagement with a pinion 46.
2. As the slide 43 travels backwards, diamond-shaped lugs 45 on the slide engage with fixed ribs 48 on the chassis. The lugs 45 deflect below the ribs 48 (Figure 18b) causing the rack 44 to miss the pinion 46. At the same time, sprung pins 47 slide in grooves 49.
3. At the position shown in Figure 18c, the slide 43 has reached the end of its backwards travel and the lugs 45 disengage from the ribs 48, allowing the slide 43 to be pushed up by the sprung pins 47. This movement causes engagement of the rack 44 and the pinion 46.

4. The tensator spring 22 now pulls the rack (Figure 18d), driving the pinion 46 which in turn drives the pusher drum (not shown) and deploys the pusher 25 to eject a test strip. The diamond-shaped lugs 45 now sit on the top side of the fixed ribs 48.

5. The rack 44 goes beyond the pinion 46 and a return spring withdraws the pusher 25. The lugs 45 drop off the ribs 48, leaving the mechanism in the rest position (Figure 18e).

The mechanism is mechanically simple and uses simple moulded components.

It is appreciated that certain features of the invention, which are for clarity described in the context of separate embodiments may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for the sake of brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

Although the invention has been described with reference to a sensor dispensing device or test device for measuring blood glucose concentration, it is to be understood that the invention is not limited to this application. The invention may be used in the determination of any analyte in a fluid, biological or otherwise, by the use of suitable reagents in the test strip. Such reagents are well known to those skilled in the art.

While the present invention has been described with

reference to specific embodiments, it should be understood that modifications and variations of the invention may be constructed without departing from the spirit and scope of the invention specified in the following claims.